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PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
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United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE
in its capacity as elected Office

Date of mailing (day/month/year) 02 May 2001 (02.05.01)	
International application No. PCT/GB00/03222	Applicant's or agent's file reference SL/SMR/OML.42
International filing date (day/month/year) 21 August 2000 (21.08.00)	Priority date (day/month/year) 19 August 1999 (19.08.99)
Applicant MARSHALL, Jeremy et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
15 March 2001 (15.03.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Pascal Piriou Telephone No.: (41-22) 338.83.38
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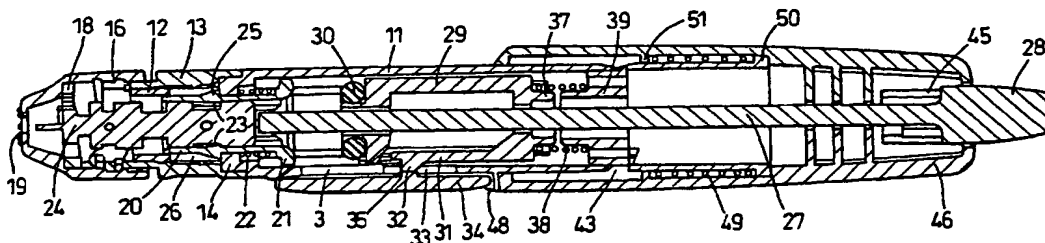
- With international search report.
- Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: LANCET



(57) Abstract: A skin pricker has a barrel (1, 11) in which a hammer (2, 29) released by a trigger mechanism (32, 34) can be shot forwards by a compressed spring (3, 38) to impact on a lancet (24) and momentarily project its tip. The rear end of the spring acts against a barrier (4, 39) adjustable axially of the barrel, so that the spring can be more or less compressed before release, causing the hammer to act with greater or lesser force on the lancet. The barrier (4, 39) may have projections (6, 8, 42) that engage in skew slots (7, 9, 43) in the barrel, so that rotation of the barrier axially adjusts it. A sleeve (44) over the rear part of the barrel instrumental in priming the device may co-operate with the projections and be rotatable to set the desired spring force.

WO 01/13794 A1

Improvements relating to

LANCET

This invention relates to medical skin piercing devices.

5 Many skin prickers have a spring-operated mechanism that projects the tip of a lancet from a leading end of a barrel. The device is held against the user's skin and "fired".

10 Usually the springs have a set rate and the force with which the lancet is urged forwards is always the same for the particular device in question. But that is not ideal.

For example some skins can be very tough, while others, particularly of infants, can be very soft and easily pierced. Therefore it is desirable to have available
15 devices which can cope with such variations.

According to the present invention, there is provided a medical skin piercing device comprising a barrel, means for carrying a lancet in the forward part of the barrel to allow the tip of the lancet to advance from a retracted to
20 a projection position, a hammer arranged when released from a rearward position to act on the rear of the lancet to cause such advance, a barrier to the rear of the hammer and adjustable axially within the barrel by cam action as a result of rotation, a spring acting between the barrier and
25 the hammer, and a trigger mechanism for holding the hammer in, and releasing it from, said rearward position with the spring compressed to a degree determined by the axial

adjustment of the barrier.

Conveniently, the barrel has slots skew to the axis of the barrel in which projections on the barrier engage. The slots may have short portions non-skew to said axis to
5 locate the projections in set positions. These projections may be on resilient formations integral with the barrier, allowing the projections to be moved radially inwards for insertion of the barrier into the barrel, the projections springing outwardly when they register with the slots.

10 Preferably, the rear portion of the barrel is encased by a captive sleeve spring urged forwardly, the sleeve having a lost motion connection through the rear end of the barrel and through the barrier to the hammer, whereby pulling back the sleeve retracts the hammer to said rearward
15 position, and release of the sleeve allows the sleeve to revert to its forward position disconnected from the hammer. The sleeve when pulled back may reveal the slots for adjustment of the projections in the slots, but preferably it will co-operate with at least one said projection and be
20 rotatable to adjust the barrier.

A nose section of the barrel will conveniently be removable to expose the lancet carrying means and allow lancets to be removed and replaced. These lancet carrying means may be a generally tubular member with limited axial
25 movement, into which a lancet fits from the forward end and spring urged rearwardly normally to maintain a lancet tip retracted.

To avoid handling a lancet after use, an ejector rod

can extend lengthwise of the barrel through the barrier and the hammer and be movable forwards to eject a lancet from the carrying means when the nose section is removed.

For a better understanding of the invention some
5 embodiments will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a diagrammatic side view, partly in section and partly in ghost, of a device for adjusting the penetration force of a medical needle or lancet, set to a maximum,

10 Figure 2 is a cross-section on the line II-II of Figure 1,

Figure 3 is a side view similar to Figure 1 but with the device set to a minimum,

15 Figure 4 is a cross-section on the line IV-IV of Figure 3,

Figure 5 is a development of a curved slot in the barrel of the device.

Figure 6 is a side view of a skin pricker,

20 Figure 7 is a longitudinal section of the skin pricker, on the line VII-VII of Figure 6,

Figure 8 is a perspective view of a spring force adjuster forming part of the pricker of Figure 6, and

25 Figure 9 is a longitudinal section of the rear portion of the pricker of Figure 6, the sectional plane being at right angles to that of Figure 7.

The device of Figure 1 has a barrel 1 with a hammer 2 loosely plugging its forward end and urged forwards by a spring 3. There is a trigger mechanism (not shown) which

holds the hammer 2 in the cocked position shown. The spring 3 reacts against an axially adjustable barrier 4 towards the rear end and when the trigger is operated it shoots the released hammer 2 forwards.

5 The barrier 4 is of thick, disc-like form with a protuberance 5 on its forward side around which the spring locates. The cylindrical surface of the disc, of a radius slightly less than the inner radius of the barrel, has two diametrically opposed projections, one being a cam 6 which
10 projects into a part-helical slot 7 in the barrel and the other being a small stud 8 which co-operates with a part-helical slot 9 complementary to the slot 7.

The slots 7 and 9 are not smooth sided over their whole lengths. At their ends and at their mid-points they divert
15 into flats 10 normal rather than skew to the axis of the barrel. This enables the cam 6 and stud 8 to locate stably at three set positions, the extreme ones being shown in Figures 1 to 4 and the intermediate one in Figure 5. It would be possible to have more than one intermediate
20 position.

The barrel 1 is of moulded plastics, giving some elasticity and resilience. This enables the barrier 4 to be pressed into place through the rear end of the barrel. It may be convenient to push it in aslant, with the cam 6
25 leading, and skew to correspond to the angle of the slot 7. Then the cam 6 can be worked up, with the adjacent portion of the barrier 4, into the slot 7, followed by the portion adjacent the stud 8 being pushed until the stud registers

with the slot 9. The barrier is then manipulated until it is co-axial with the barrel 1. It will be kept substantially square on to the axis by the spring 1, by the cam 6 in the slot 7 and the stud 8 in the slot 9, and by the co-
5 operation of its cylindrical end surface with the inner surface of the barrel (which will have reverted to its proper shape following any distortion suffered as a result of inserting the barrier).

The cam 6 is accessible, and the user can shift it
10 along the slot 7 to cause the barrier 4 to increase or decrease the compression of the spring 3. When the barrier is forwards, as in Figure 1, there is maximum initial compression, and the hammer 2 is propelled forwards with maximum force. Correspondingly, when the barrier is
15 rearwards, as in Figure 3, the hammer is propelled forwards with lesser force.

A practical example is shown in Figures 6 to 9 in which a skin pricker has a cylindrical barrel 11 with a reduced forward end portion 12 over which fits a connecting collar
20 13, screwing to the barrel at shoulder 14. A nose piece 15 attaches to the collar 13, being fitted over a reduced forward end portion 16 before being trapped by a non-return formation. But although captive, it can still be rotated, using grip 17, to adjust its axial position within limits.
25 An internal ring 18 determines this, and thereby controls the amount by which a lancet tip will project through aperture 19.

The barrel portion 12 receives and guides a tubular

lancet holder 20 whose rear out-turned rim 21 is initially held back from the shoulder 14 by a light spring 22. At about its mid-length the holder has shallow internal projections 23 which retain a lancet 24 snapped in from the front end, and more pronounced external barbs 25 which snap into slots 26 in the portion 12 from the rear, allowing limited axial travel of the holder 20. Initially, the tip of the lancet 23 is retracted within the nose piece 15.

An ejector rod 27 extends co-axially through the barrel and beyond to the rear, and when the collar 13, with the nose piece 15, is removed it can be pressed by rear end knob 28 to snap the lancet forwardly out of the holder 20.

A hammer 29 has a generally cylindrical hollow body through which the rod 27 freely passes, and with a cylindrical spigot at its forward end around which snaps a rubber ring 30. When released, this will hit the rim 21 to drive the holder 20 and thus the lancet forwards. This ring device serves as a damper and the rubber ensures virtually silent operation. A narrow U-shaped slot in the cylindrical wall of the hammer forms a flexible finger 31 which, at its free forward end, has an outwardly projecting stud 32 engaged in a slot 33 in the barrel. This is part of a trigger mechanism, whose other part is an oval button 34 mounted over this region of the barrel and with an inner projection 35 that co-operates with the stud 32. Pressure on the button flexes the finger 31 in to release the stud 32 from the slot 33 and allows the hammer to shoot forwards. The finger 31 can almost immediately recover its original

attitude with the stud 32 entering another slot 36.

At its rear end, the hammer 29 has a short cylindrical extension 37 which locates the forward end of a helical drive spring 38, whose rear end reacts against a force
5 adjuster 39.

The force adjuster is best seen in Figure 8. It has a cylindrical plastics body 40, through which the rod 27 will freely pass, and on the outside of that two diametrically opposed integral loops 41 of arcuate form, each
10 subtending an angle of about 90°. The outer surfaces of the loops are of a radius corresponding to the interior of the barrel 11 but the loops are thin enough to be deformed radially inwards, to allow outwardly projecting studs 42 at the centres of those outer surfaces to be depressed suffi-
15 ciently to enable the adjuster to be entered into the rear of the barrel. When the studs reach opposed inclined slots 43 in the barrel the loops 41 spring outwards, and the studs are captive.

A sleeve 44 sheaths the rear end of the barrel 11 and
20 provides at its rear end a guide slot 45 for the knob 28 of the rod 27.

The sleeve 44 is made from two substantially semi-cylindrical halves, one half 46 having at its leading end a recess 47 matching in shape the rear part of a low wall 48
25 proud of the barrel 11 and closely surrounding the trigger button 34. The sleeve 44 is urged forwardly by a helical spring 49 around the barrel, acting between a rear end flange 50 on the barrel and an annular rib 51 internal of

the sleeve. Normally, the spring 49 causes the sleeve 44 to be located with the wall 48 nesting in the recess 47.

The ejector rod 27 is reduced to semi-circular cross-section over much of its length and along this portion lies
5 a complementarily shaped, shorter, loading rod 52 with a certain freedom of axial movement relative to the rod 27. This has a rear end head 53 which is trapped by internal webs 54 of the sleeve 44 and it passes through the force adjuster 39 into the hammer 29, where barbs or spring
10 fingers engage the rear wall of the hammer. Initially, both the hammer 29 and the sleeve 44 are in their forward positions. But once the lancet has been loaded, the sleeve 44 is pulled back, and the loading rod 52, drawn by its head 53, pulls back the hammer 29, the stud 32 being temporarily
15 pressed inwards by the bridge between the slots 33 and 36. Then the hammer is trapped in its rearward ready-to-fire position and the sleeve 44 can be allowed to spring forwards, taking the rod 52 with it and freeing the hammer 29 for forward movement.

20 When the sleeve 44 is in its rearward position, it can be rotated to operate the force adjuster 39, being turned one way to move the adjuster forwards and increase the initial spring force, and the other way to move the adjuster rearwardly and reduce that initial force. At least one of
25 the studs 42 will be proud of the barrel 11 and can be positively engaged by a formation within the forward end of the sleeve, behind inturned rib 55. The amount of force adjustment can be gauged by the amount of rotation. Once

the sleeve is released to spring forwards, it is guided into its original alignment by the recess 47 meeting the wall 48.

The sleeve 44 could be arranged to expose at least one of the studs 42, so that the user could directly manipulate the force adjuster. But that might prove awkward in practice.

In these figures the slots in the barrel are shown without flats, but their angle is such that the studs will remain where positioned by friction. But flats could be provided if desired.

Claims

1. A medical skin piercing device comprising a barrel, means for carrying a lancet in the forward part of the barrel to allow the tip of the lancet to advance from a retracted to a projecting position, a hammer arranged when released from a rearward position to act on the rear of the lancet to cause such advance, a barrier to the rear of the hammer and adjustable axially within the barrel by cam action as a result of rotation, a spring acting between the barrier and the hammer, and a trigger mechanism for holding the hammer in, and releasing it from, said rearward position with the spring compressed to a degree determined by the axial adjustment of the barrier.
2. A device as claimed in Claim 1, wherein the barrel has slots skew to the axis of the barrel in which projections on the barrier engage.
3. A device as claimed in Claim 2, wherein the slots have short portions non-skew to said axis to locate the projections in set positions.
4. A device as claimed in Claim 2 or 3, wherein the projections are on resilient formations integral with the barrier, allowing the projections to be moved radially inwards for insertion of the barrier into the barrel, the projections springing outwardly when they register with the slots.
5. A device as claimed in any proceeding claim, wherein the rear portion of the barrel is encased by a captive

sleeve spring urged forwardly, the sleeve having a lost motion connection through the rear end of the barrel and through the barrier to the hammer, whereby pulling back the sleeve retracts the hammer to said rearward position, and
5 release of the sleeve allows the sleeve to revert to its forward position disconnected from the hammer.

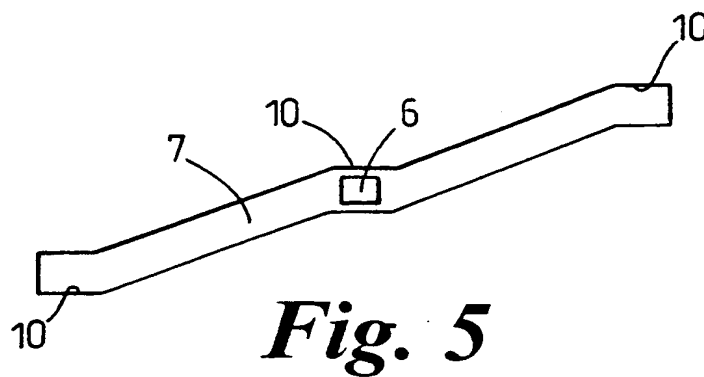
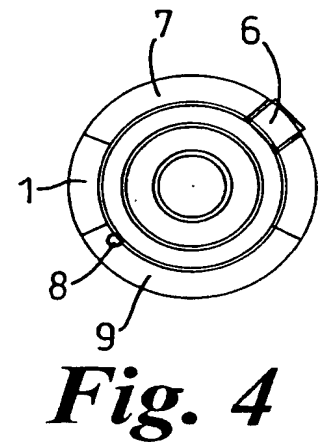
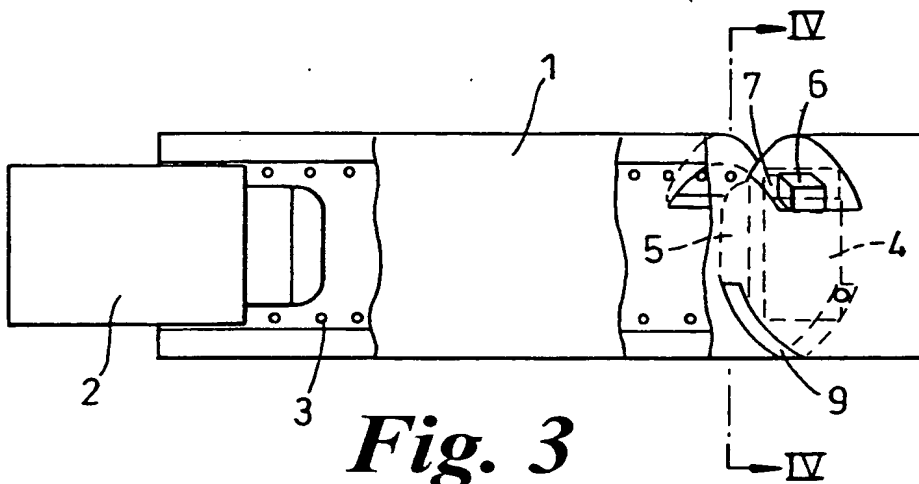
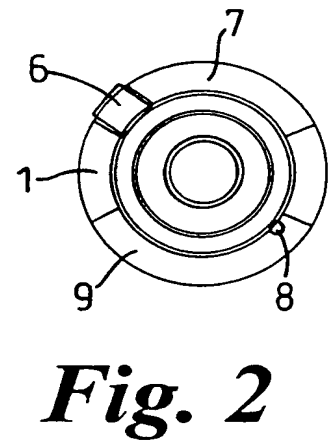
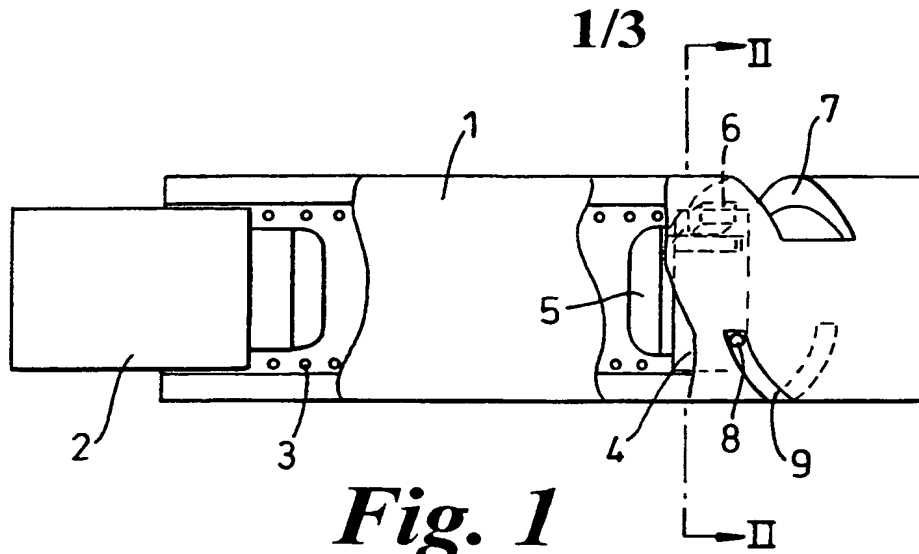
6. A device as claimed in Claim 5 as appendant to Claim 2, 3 or 4, wherein the sleeve when pulled back reveals the slots for adjustment of the projections in the slots.

10 7. A device as claimed in Claim 5 as appendant to Claim 2, 3 or 4, wherein the sleeve when pulled back co-operates with at least one said projection and is rotatable to adjust the barrier.

8. A device as claimed in any preceding claim, wherein a
15 nose section of the barrel is removable to expose the lancet carrying means and allow lancets to be removed and replaced.

9. A device as claimed in Claim 8, wherein the lancet carrying means is a generally tubular member with limited axial movement, into which a lancet fits from the forward
20 end and spring urged rearwardly normally to maintain a lancet tip retracted.

10. A device as claimed in Claim 9, wherein an ejector rod extends lengthwise of the barrel through the barrier and the hammer and is movable forwards to eject a lancet from the
25 carrying means when the nose section is removed.



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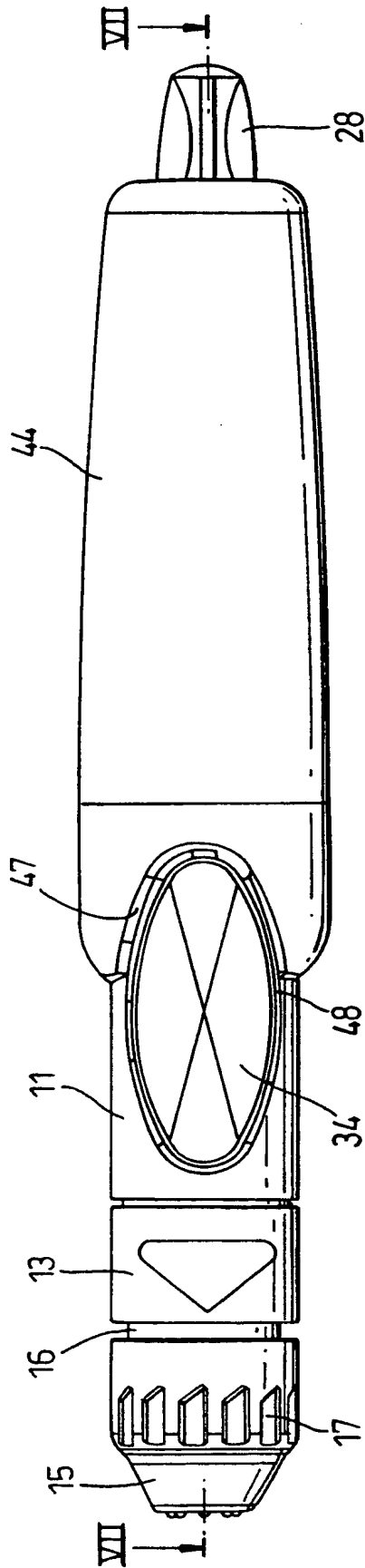


Fig. 6

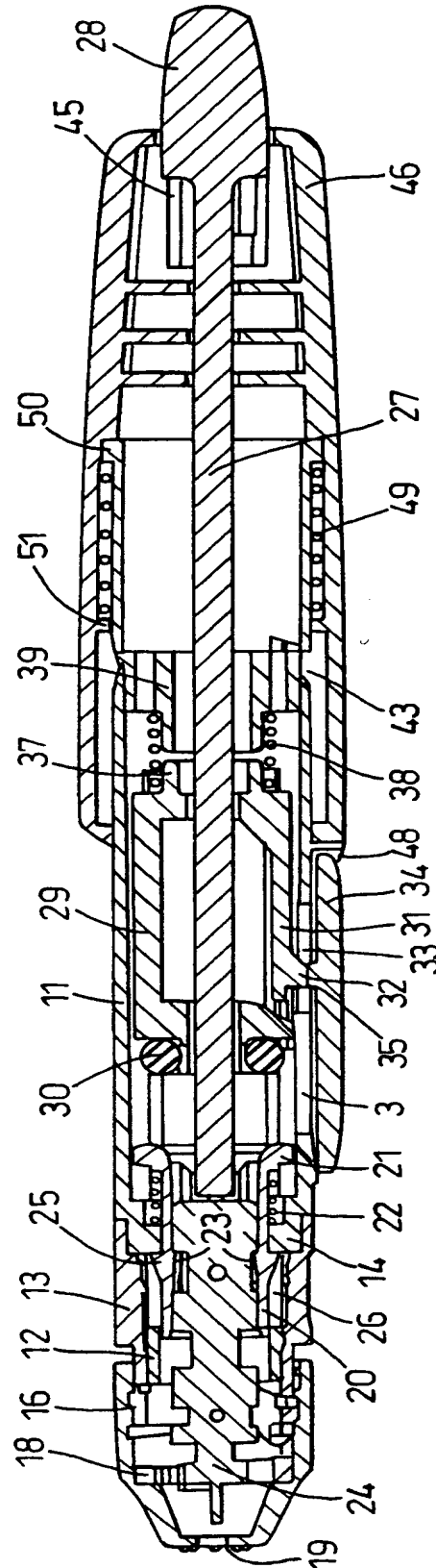
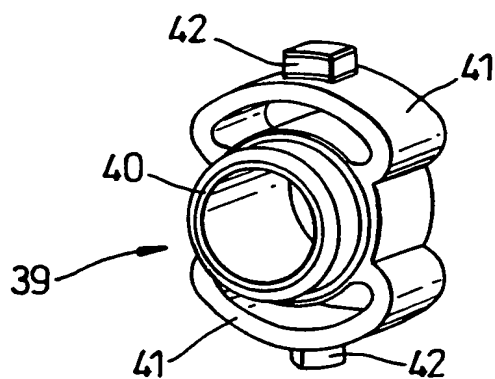
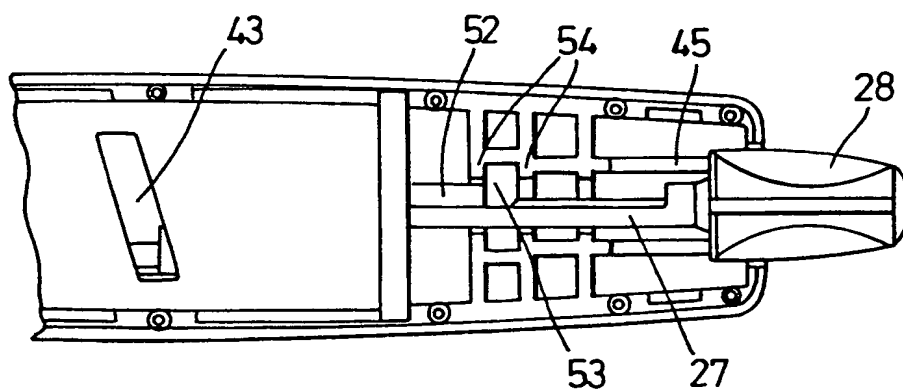


Fig. 7

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*Fig. 8**Fig. 9*

INTERNATIONAL SEARCH REPORT

International Application No

PC 00/03222

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/145

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 895 147 A (BODICKY ET AL.) 23 January 1990 (1990-01-23) column 5, line 42 -column 8, line 24 figures	1
A	---	8
Y	US 5 569 189 A (PARSONS) 29 October 1996 (1996-10-29) column 8, line 1 -column 12, line 4 figures 5-6A	1
A	---	1,8,9
	US 5 871 494 A (SIMONS ET AL.) 16 February 1999 (1999-02-16) column 11, line 16 -column 13, line 20 -----	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
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- *X* document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

8 December 2000

Date of mailing of the international search report

18/12/2000

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Chen, A

INTERNATIONAL SEARCH REPORT

Intern 1al Application No


PCT 00/03222

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 4895147	A	23-01-1990	NONE		
US 5569189	A	29-10-1996	US	5499972 A	19-03-1996
			US	5704911 A	06-01-1998
			AU	5293393 A	26-04-1994
			WO	9407554 A	14-04-1994
US 5871494	A	16-02-1999	DE	19855443 A	17-06-1999
			GB	2331934 A	09-06-1999

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SL/SMR/OML.42		FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB00/03222		International filing date (day/month/year) 21/08/2000	Priority date (day/month/year) 19/08/1999	
International Patent Classification (IPC) or national classification and IPC A61B5/145				
Applicant OWEN MUMFORD LIMITED et al.				
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>				
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input checked="" type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application 				
Date of submission of the demand 15/03/2001		Date of completion of this report 25.07.2001		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Alvazzi Delfrate, S Telephone No. +49 89 2399 7450		



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/03222

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-9 as originally filed

Claims, No.:

1-10 as originally filed

Drawings, sheets:

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/03222

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims 1-10
	No: Claims
Inventive step (IS)	Yes: Claims 1-10
	No: Claims
Industrial applicability (IA)	Yes: Claims 1-10
	No: Claims

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/03222

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The invention relates to a medical skin piercing device.

Document **US-A-5 871 494 (=D1)**, which is regarded as closest prior art, discloses a medical skin piercing device comprising a barrel (Fig.5B, ref.526), means (ref.542, ref.552) for carrying a lancet (ref.216) in the forward part of the barrel to allow the tip of the lancet to advance from a retracted to a projecting position, a hammer (ref.542) arranged, when released from a rearward position, to act on the rear of the lancet to cause such advance, a barrier (ref.554) to the rear of the hammer, a spring (ref.532) acting between the barrier and the hammer, a trigger mechanism (ref.538) for holding the hammer in, and releasing it from.

Object of the invention is to provide a medical skin piercing device which is available of being set up in such a way that the force with which the lancet is urged forwards is different according to the skin of the patient (tough or very soft).

To solve said technical problem a device as defined in claim 1 is provided.

The essence of the invention resides **in a barrier adjustable axially within the barrel by cam action as a result of rotation**, which determines the degree of compression of the spring when the hammer is in its rearward position.

Document **US-A-4 895 147**, which discloses a lancet injector, does not even mention the problem of setting up the lancet force for different patient's skins and document **US-A-5 569 189** shows a screw for selectively shorten or lengthen the channel of the compression spring but for a spring actuated **needleless hypodermic injection** assembly. Therefore, there is no hint to combine the two (Y) documents.

Independent claim 1 meets the requirements of Articles 33(2)-(4) PCT.

Claims 2 to 10 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/03222

Re Item VII

Certain defects in the international application

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document **D1** is not mentioned in the description, nor is this document identified therein.
2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
3. In the present case it would be appropriate to draft the independent claim in the two-part form in accordance with Rule 6.3(b) PCT, with those features known in combination from the prior art (document D1) being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).